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**Trial Affidavit of Beatrice Manning**

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE LITIGATION**

**MDL No. 1456**

**THIS DOCUMENT RELATES TO:  
ALL CLASS ACTIONS**

**CIVIL ACTION: 01-CV-12257-PBS**

**Judge Patti B. Saris**

**DECLARATION OF BEATRICE E. MANNING, PH.D.**

1. My name is Beatrice Manning and I reside at 114 Packard Road, Stow, Massachusetts 01775.
2. I am currently working on a Master of Arts -- Research -- Specialty in Ethics (expected 2007) at Andover Newton Theological School. Additionally, I have attached to this affidavit my resume setting forth the details of my education, work experience and publications.
3. I was an employee of the Schering-Plough Corporation (SP) for slightly over five years (Spring 1997- Spring 2002).
4. While employed by SP, I and many other SP employees were assigned to work for the disease management unit of SP, a wholly-owned subsidiary named Integrated Therapeutics Group (ITG).
5. My position at ITG was the manager of clinical opportunities as shown by chart number 06.00 at SW0638453 of Exhibit 407. As manager of clinical opportunities I participated in meetings and discussions with SP officers and employees regarding SP's managed care business operations, marketing and contracting. Also, as manager of clinical opportunities I had access to and reviewed SP memoranda and documents regarding the operations, marketing and

contracting for SP drugs, including SP's line of albuterol inhalants, with managed care customers such as IPAs, HMOs and PBMs. The facts testified to in this affidavit are based upon my personal knowledge acquired in the regular course of business in my employment with SP and in my position as manager of clinical opportunities of ITG.

6. ITG's offices were located in SP's headquarters in Kenilworth, New Jersey. ITG operations were totally financed by SP. ITG was totally operated and controlled by SP officers and employees. The SP officers who directed and controlled ITG were Raul Cesan, Richard Zahn, Len Camarda, and Roch Doliveux.

7. During the final four years of my employment with SP, I was a whistleblower against SP for illegal marketing practices that resulted in a global resolution during the summer of 2004 with the United States Attorney for the Eastern District of Pennsylvania that included the following components: (1) SP's wholly-owned subsidiary, Schering Sales Corp., pled guilty to a violation of the Anti-Kickback Statute for paying a kickback to a customer in exchange for preferred formulary treatment of Claritin and SP paid the fine of \$52.5 million assessed for the violation; (2) SP agreed to settle its False Claims Act liability and to pay to the United States, 50 Medicaid programs, and certain Public Health Service entities \$292,969,482 for Schering's failure to report its true best price for Claritin; and (3) SP entered into a Corporate Integrity Agreement with DHHS to correct its government pricing reporting failures.

8. SP used an intricate scheme to cheat Medicaid out of hundreds of millions, if not billions, of dollars. SP evaded its responsibility to charge the U.S. government and its beneficiaries the lowest price it charged to the private sector, i.e., the best price required by federal law. Most of the scheme was carried out using ITG. The scheme, which centered on SP's

blockbuster drug Claritin, had three major prongs that served as “kick-backs” and hidden rebates and/or discounts.

9. The first prong: ITG provided free or well-below-cost health management services to HMOs that put Claritin on formulary. These services were not provided to Medicaid clients, including Medicaid clients enrolled in those same HMOs. The value of these services was not included in the best-price calculation SP used to establish Medicaid pricing. ITG would sign a contract with the HMOs and this contract would be ostensibly totally separate from the rebate contracts that SP would sign with the managed care organizations. Medicaid auditors would review the rebate contracts with SP (not ITG) and thus would never see the additional “kick-backs” or hidden rebates/discounts SP gave through ITG. The role of ITG services are reflected in Exhibit 565, a draft memo from Linda Zhou, who was then the head of SP’s Contracts and Pricing division. In this memo, Zhou is making the “business case” for further investment into ITG’s computer capacity. On page 2, under Roman numeral I, Zhou states, “ITG’s services complement and enhance Schering’s pharmaceutical products and meaningfully differentiate them from the competition. Thus, they provide our primary means of implementing the strategy to *compete on a basis other than price*.” On the next page under the section of “Increased Profitability” Zhou stated, “By allowing us to compete on a basis other than price, ITG has increased Schering Lab’s profitability. Total discounts as a % of contracted gross sales has declined in 1996 from 23% in 1996 to 17% currently. At 1998 LE sales levels, this equates to annual savings of \$222 million.”

10. The second prong: ITG also used “partnership fees” in its relationship with PBMs. ITG would pay the PBMs for studies or analyses of their data sets of patients in amounts of “partnership fees” that were well above their actual cost.


11. The third prong: SP, through ITG, “gave” the managed care organizations nominally priced drugs, including Warrick albuterol inhalants, to equalize the difference between the “price” of Claritin and the “price” of Allegra or to create value to induce the MCO to enter into a contract.

12. As part of the strategy to *compete on a basis other than price*, SP relied on the value of spreads created by high AWP's and reimbursement by Medicaid, Medicare and third party payors on those drugs. Managed care organizations and could further enhance their “discounts” by reselling drugs, including albuterol, which they had been “given” as nominally priced drugs in connection with the scheme to avoid Medicaid rebates and equalize pricing of Claritin in managed care contracts. SP did not account for the value of the hidden rebates/discount given from the nominal priced albuterol in SP sales or rebate/discount records. Essentially, SP was keeping two sets of accounting books, one for SP, one for ITG. SP hid the value of the ITG services, “partnership fees” and nominal pricing rebates/discounts in ITG's books.

13. As manager of clinical opportunities, I witnessed marketing preparations and presentations to managed care organizations. During the time I worked at SP, I observed preparations of presentations for field forces to market the reimbursement spreads created by false AWP's, to show the value of the nominally priced drugs being “given” as part of a managed care contract. In the presentations I observed the sales forces making such presentations were careful not to leave any presentation material behind after making such marketing presentations and in office preparation of the presentations did not include distribution of these materials to staff other than those who would make the presentations.

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I declare under penalty of perjury that the foregoing is true and correct.

  
Beatrice E. Manning

Dated: 10/27/2006

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## BEATRICE E. MANNING, PH.D.

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### PROFILE

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- *Social science and theological ethicist who acted as whistleblower in \$350M fraud recovery*
- *Creative, responsive leader with strong analytic and people skills*
- *Designer of major health care reforms over the past two decades in public health and the pharmaceutical, managed care and insurance industries*
- *Committed to life-long learning and sharing of knowledge*

### EDUCATION & HONORS

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ANDOVER NEWTON THEOLOGICAL SCHOOL *Master of Arts- Research (expected 2007)*  
*Specialty in Ethics*

*Thesis: Alienation in the Work Place: A Theo-Ethical Sociological Perspective*  
UNIVERSITY OF CONNECTICUT *Doctor of Philosophy in Sociology*

SYRACUSE UNIVERSITY *Master of Social Work*  
UNIVERSITY OF CONNECTICUT *Bachelor of Arts with Honors*

PHI BETA KAPPA, PHI KAPPA PHI, DISSERTATION FELLOWSHIP

### EXPERIENCE

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**TESTIMONY BEFORE UNITED STATES SENATE, COMMITTEE ON FINANCE**  
*Medicaid Waste, Fraud, and Abuse: Threatening the Health Care Safety Net June 29, 2005*

**FITCHBURG STATE COLLEGE, FITCHBURG, MA**  
*Adjunct Graduate Faculty, Department Communications Media 2003 - present*

**KEAN UNIVERSITY, UNION, NJ**  
*Adjunct Graduate Faculty, Department of Public Administration 2001*

**INTEGRATED THERAPEUTICS GROUP, SCHERING-PLOUGH, KENILWORTH, NJ**  
*Health Care Solutions Development 1997 - 2002*

I created tools to identify at risk populations, and evaluated outcomes. I identified health management opportunities, developed research projects with academic centers.

- Created evaluation tool and data collection mechanism for program to provide asthma health care to homeless mothers and children living in NYC shelters and advised on social aspects of asthma
  - Identified high risk asthma patients with comorbidities and demonstrated treatment alternative that significantly reduced hospitalizations and emergency room visits for Medicaid and commercial patients (*J. of Allergy & Clinical Immunology* March 2004)
  - Quantified medical and pharmaceutical utilization patterns of patients using highest cost pharmaceutical products ('01 Am. Coll. of Allergy, Asthma, Imm. presentation)
  - Demonstrated 30% decrease in upper respiratory infections among allergy patients when they use allergy medications ('01 Am Col of All, Asthma, Imm presentation)
  - Identified increased allergy risk among patients with depression and demonstrated decreased use of mental health resources if allergies are treated
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### EXPERIENCE (CONTINUED)

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- Defined cost shifts from pharmaceutical movement to over-the-counter (*Drug Benefit Trends*, March 2002)

#### **AETNA US HEALTHCARE, MIDDLETOWN, CT**

*Manager, Health Information Bureau 1996 - 1997*

Directed quality of care measurement, outcomes, and cost/benefit analyses, including a quality improvement study design for NCQA, in cooperation with senior medical staff

- Conducted study of mental health costs and financing trends (APHA presentation)
- Conducted hospital utilization study of HMO and POS networks, including identifying cost drivers, determining ambulatory care sensitive use rates, and comparing plans to national standards; demonstrated to medical leadership the value of this approach compared to traditional hospital length-of-stay monitoring
- Designed and conducted quality improvement studies for prenatal care, ulcer treatment and influenza immunization levels
- Instructed medical and quality directors in study design and basic statistical methods needed to meet NCQA accreditation standards

#### **ASTRA MERCK, INC., WAYNE, PA**

*Consultant, Health Economics and Customer Services 1995 - 1996*

- Identified ways in which pharmaceutical prescribing patterns vary by financing arrangements, geographic area, physician specialty and provider saturation
- Identified differential measures of market share (doses, prescriptions, dollars) and implications of using each

#### **NEW JERSEY STATE DEPARTMENT OF HEALTH, TRENTON, NJ**

*Director, Policy Development, Research and Evaluation 1989 - 1995*

*Assistant Director for Hospital Reimbursement Policy Development 1988 - 1989*

*Project Specialist 1987 - 1988*

*Health Economics Research Specialist 1985 - 1987*

- Managed evaluation of \$40 million of primary care initiatives, including development of population based measures
- Designed financial incentives to encourage hospitals to carry out public health policies, including training primary care providers and accepting seriously mentally ill patients
- Designed primary care oriented managed care program for children and low income uninsured families, including subsidy levels and cost of various benefit options
- Steered reform of small group insurance market, including risk pool management, benefit design and co-payment variation developing plans that included mental health parity
- Developed graduate medical education cost predictive model with 50% improvement in predictive power over Medicare and previous New Jersey approaches
- Authored grant proposal funded by Robert Wood Johnson Foundation to create single-point-of-entry system for long-term care



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### EXPERIENCE (CONTINUED)

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- Chaired department's human subjects review board
- Developed DRG rates directing \$8 billion in annual payments to hospitals
- Outsourced, wrote and administered multi-million-dollar RFPs for research, information management and auditing
- Formulated statewide strategic health plan including sections on mental health, addictions, primary care sections, and women's health, coordinated appropriate sections with State Department of Social Services

#### **MASSACHUSETTS HEALTH DATA CONSORTIUM, WALTHAM, MA**

*Consultant (part-time) 1991 - 1993*

- Principal investigator for study modeling financial and service development impact of various payment grouping approaches on Boston teaching hospitals
- Developed outpatient surgery data sets, including Ambulatory Patient Groupings

#### **JERSEY CITY STATE COLLEGE, JERSEY CITY, NJ**

*Assistant Professor of Sociology 1981 - 1985*

Graduate and undergraduate teaching in social problems, statistics, urban, social work, human services for the elderly, family, community, introduction; designed core curriculum, established computer literacy and internship requirements

#### **CAPITOL REGION COUNCIL OF GOVERNMENTS, HARTFORD, CT**

*Economic Development Planner 1980 - 1981*

- Developed methodologies adopted by state and local governments and used to define enterprise zones
- Modeled local revenue changes resulting from economic development projects

#### **ANNHURST COLLEGE, WOODSTOCK, CT**

*Adjunct Instructor of Sociology 1978 - 1980*

#### **MOHEGAN COMMUNITY COLLEGE, NORWICH, CT**

*Adjunct Instructor of Sociology 1978 - 1980*

#### **UNIVERSITY OF CONNECTICUT, STORRS, CT**

*Project Researcher 1976 - 1978, Graduate Teaching and Research Assistant 1974 - 1976*

Directed health needs and practices study & taught introductory and social problems courses

#### **SPRINGFIELD JUVENILE COURT CLINIC, SPRINGFIELD, MA**

*Clinical Social Worker 1972 - 1973*

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### PROFESSIONAL ASSOCIATIONS

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American Public Health Association, American Sociological Association, National Association of Social Workers, National Women's Health Network, Past-President (1988-9) New Jersey Sociological Society, New York State Sociological Association

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### PUBLICATIONS

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#### ARTICLES

- Corren J, Manning BE, Thompson SF, Hennessy S, Strom BL. Rhinitis Therapy and the  
2004 Prevention of Hospital Care for Asthma: A Case-Control Study. The Journal of Allergy and Clinical Immunology. 113 (3).
- Gianfrancesco F, Manning BE, Wang R. Effects of Rx to OTC Switches on Consumer Out-of-  
2002 Pocket Health Care Costs and Medical Service Use. Drug Benefit Trends, March.
- Manning BE. Comments on Paying Physicians as Agents: Fee-For-Service, Capitation, Or  
1995 Hybrids? Mark V. Pauly. Health Care Policy and Regulation. Edited by T. Abbott. Kluwer Academic Publishers.
- Averill RF, McGuire TE, Manning BE, Fowler DA, Horn SD, Dickson PS, Coye MJ, Knowlton DL,  
1992, Bender JA. A Study of the Relationship between Severity of Illness and Hospital Costs in New Jersey Hospitals. Health Services Research. 27 (5).
- Manning BE, Turner NE. Chapter 7: Participation in the Political Sector. In Sex Roles and  
1986 Social Patterns. Edited by F. Boudreau, R. Sennott, and M. Wilson. Praeger Publishers.
- Hill G, Manning BE. Present and Future Fiscal Condition of the Capitol Region. Connecticut  
1981 Government. 32 (1).

#### IN PROGRESS

- "Whistleblowing" entry in Encyclopedia of Activism and Social Justice. Sage Publishing. (entry accepted, expected publication 2007)
- "Pharmaceutical Practices, Health Equality, and Work Place Ethics" with C. Alcorn (accepted for presentation at Nov. 2006 meeting of American Public Health Association)

#### PRESENTATIONS AT PROFESSIONAL MEETINGS (SELECTED)

- Manning, BE, "Terrorism: A Postmodern Perspective," New York State Sociological Association  
2004 Association annual meeting, Oswego, NY.
- Corren, J., Manning, B., Thompson, S., Hennessy, S., Strom, B., "Intranasal Corticosteroids Reduce  
2003 Risk of Hospitalizations for Asthma in Patients with Asthma and Concomitant Allergic, Rhinitis," American Academy of Allergy Asthma and Immunology annual meeting, Denver, CO.
- Zhang Q, Manning, BE, Garavaglia S, Alcorn CM, Yang T, Thompson S, Corren J,  
2001 "Approximating Treatment Effects in Commercial Claims Data," American Statistical Association International Conference on Health Policy Research, Boston, MA.
- Corren J, Manning BE, Zhang Q "Treatment of Allergies Decreases URI Occurrences" American  
2001 College of Allergy Asthma and Immunology Annual Meeting, Orlando, FL.
- Manning BE, "Pharmacy and Medical Costs of Patients Treated with Second-Generation

2001 Antihistamines " American College of Allergy, Asthma and Immunology Annual Meeting, Orlando, FL.

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Lash A, Alcorn CA, Manning BE "The Establishment, Optimal Organization, Placement, and  
2000 Use of an Analytics Team Responsible to Business Units and the Field Force"  
Pharmaceutical Management Sciences Association Annual Meeting, Orlando, FL.

Manning BE, Heslep H, Greenberg M "Changes in the Financing of Mental Health and  
1996 Addictions Treatment: Where They Came From, Where They're Going " Mental Health  
Section, American Public Health annual meeting, NY, NY.

Manning BE, Chair for "Managed Care." Health Care Policy and Regulation Annual Conference  
1996 Lake George, NY.

Manning BE, Chair for "Managed Care Symposium." Rutgers Center for Research in Regulated  
1996 Industries. Newark, NJ

Manning BE, Discussant for "Price Regulation of the Pharmaceutical Industry." Advanced  
1995 Workshop in Regulation and Public Utility Economics Annual Conference, Newport, RI.

Manning BE, Vivona B, Fiorentino NF, Caldwell W, "Health Access New Jersey:  
1994 Development of a Subsidized Insurance Program." Health Administration Section,  
American Public Health Association annual meeting, Washington, DC.

Albiral Gomez P, Manning BE, Martin RM, "The Need for a Multicultural Health Care Policy:  
1994 Perspective: Building a Diverse Health Care Policy Team." Latino and Women's,  
Caucuses (joint session), American Public Health Association annual meeting, Washington  
DC.

Moyer NC, Manning BE, Caldwell W, "Creating Alternatives to Nursing Home Care: A  
1994 Conceptual Framework for Projecting and Controlling Medicaid Costs." Community  
Health Planning and Policy Development Section, American Public Health Association  
annual meeting, Washington, DC.

Manning BE, "Use of Analysis of ACS Rates in Planning and Evaluation in State Government."  
1993 Community Health Planning and Policy Development Section, American Public Health  
Association annual meeting, San Francisco, CA.

Manning BE, Fiorentino NL, Featherstone NL, Siegel B, "Health and Prevention versus  
1993 Biology and Illness Models: Integrating Mental Health and Public Health into New  
Jersey's Comprehensive Health Plan." Mental Health Roundtable, American Public  
Health Association annual meeting, San Francisco, CA.

Featherstone NL, Siegel B, Black KJ, Manning BE, Ryan EA, "New Jersey - Leading the  
1993 Way in Health Insurance Reform." Health Administration Section, American Public  
Health Association annual meeting, San Francisco, CA.

Manning BE. Moderator for session, " Assisted Living: New Regulations and How to Implement  
1993 them." New Jersey Gerontological Institute conference on Housing Options for the Older  
Adult, New Brunswick, NJ.

Dickson PS, Davis AR, Fowler DA, Noggoh EA, Manning BE, "Analysis of 1992

1993 Outpatient Service and Cost in New Jersey Hospitals." Health Administration Section, American Public Health Association annual meeting, San Francisco, CA.

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Fiorentino NL, Siegel B, Featherstone NL, Manning BE, Webster G., "Decreasing Use of  
1993 Alcohol and Tobacco by Increasing Price: A Case Study in New Jersey." Alcohol, Tobacco and Other Drugs Section, American Public Health Association annual meeting, San Francisco, CA.

Manning BE, Knauf R, Noggoh EA, Davis AR, "Using Statistics to Measure the Costs of  
1992 Training Physicians." Statistics and Medical Care Sections (joint session), American Public Health Association annual meeting, Washington, DC.

Davis AR, Manning BE, "Analysis of Components of Graduate Medical Education." Health  
1992 Administration Section, American Public Health Association annual meeting, DC.

Manning BE, Knauf R, Noggoh EA, Davis AR, "Predicting and Standardizing Payment for  
1991 the Costs of Graduate Medical Education." Statistics and Medical Care Sections (joint session), American Public Health Association annual meeting, Atlanta, GA.

Dickson PS, Dunston FJ, Goodrich GE, Manning BE, Scioli J, Featherstone NL, Siegel B, Weiss A,  
1991 "Certificate of Need and Rate-Setting: Competing or Complementary Regulatory Approaches to Control Capital Costs?" Community Health Planning and Policy Development Section, American Public Health Association annual meeting, Atlanta, GA.

Weiss AF, Dunston FJ, Goodrich GE, Dickson PS, Featherstone NL, Manning BE, Moss DK,  
1991 Siegel B. "Cost Containment and Access: Lessons from the New Jersey Reimbursement System." Health Administration Roundtable, American Public Health Association annual meeting, Atlanta, GA.

Manning BE. Discussant for session, "The Family - Problems and Possibilities: A Sociological  
1987 View." New Jersey Sociological Society annual meeting, Trenton, NJ.

Manning BE. Discussant for session, "Research in Non-academic Settings." New Jersey  
1986 Sociological Society annual meeting, Trenton, NJ.

Manning BE. "Nurses on Strike: A Case Study." Sociologists for Women in Society and the  
1984 Society for the Study of Social Problems annual meetings (joint session), San Antonio, TX.

Brown JA, Manning BE. "The Media's Presentation of Jonestown: The Social Construction of  
1979 of Individualism." Annual meeting of the Society for the Study of Symbolic Interactionism, Boston, MA.

## MONOGRAPH

Manning BE. Nurses on Strike: A Case Study. Doctoral Dissertation. University of Connecticut. On  
1982 microfilm.